


RAPS 2008
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& exhibition
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Hynes Convention Center

**CBER Executive Staff
Briefing: Structured
Product Labeling
(SPL)**



RAPS REGULATORY AFFAIRS
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CBER Executive Staff Briefing: Structured Product Labeling

- Content of Labeling
- Electronic Drug Establishment
Registration and Drug Listing

CBER Content of Labeling Requirement

- Health Level Seven (HL7) Structured Product Labeling (SPL) in XML to be the only acceptable presentation in electronic format for the submission of content of labeling beginning **October 15, 2008**.
- Applies to the content of labeling with original submissions, supplements, and annual reports.
- Content of labeling in SPL format is not required for annual reports unless there are changes from the currently approved SPL labeling.

***Submit if this is the first time submitting to FDA in SPL format*



CBER Memorandum to Docket 92S-0251

- Notification of CBER's readiness to accept electronic regulatory submissions for content of labeling.
 - Pursuant to 21 CFR part 11.2(b)(2)

See:
www.fda.gov/oc/datacouncil/spl.ht

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Structured Product Labeling (SPL)

- Electronic labeling standard developed by Health Level 7 (HL7)
 - Utilizes eXtensible Markup Language (XML)
 - Machine readable tags to improve search functionality across systems
 - Usability across multiple database platforms
 - Promote electronic health information initiatives
 - Enhance search capabilities

XML Structured Content

```
<time value="20080207"/>
  <assignedEntity>
    <id extension="VP00019"
    root="2.43.106.1.925856.8.422"/>
    <representedOrganization>
      <name>Greatest Pharmaceuticals</name>
      <addr>Metropolis, MA, USA</addr>
    </representedOrganization>
  </assignedEntity>
</author>
```

Label Negotiations

- Labeling currently accepted in Word and PDF.
- Continue to submit Word version with SPL labeling.
 - SPL to PDF/Word Conversion Tool
 - Currently in testing
 - Would eliminate the requirement to submit content of labeling in Word

Supporting Documents for SPL Content of Labeling

- [SPL Docket 92S-0251 - Content of Labeling - CBER](#)
 - Notification of CBRE's readiness to accept electronic regulatory submissions for content of labeling.
 - Pursuant to 21 CFR part 11.2(b)(2)
- [Guidance to Industry: *Providing Regulatory Submissions in Electronic Format -- Content of Labeling \(Final\)*](#)

****** Documentation for creating and viewing SPL files may be found through the FDA web site at: www.fda.gov/oc/datacouncil/spl.html

Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (7/11/08)

- Voluntary Pilot Program (Release 4 only)
 - NDC Labeler Code Request
 - Establishment Registration
 - Drug Listing/Content of Labeling
- Guidance covers:
 - How to submit the information electronically in Structured Product Labeling (SPL) files, using a defined terminology.
 - Transition from paper-based to electronic submissions of drug establishment registration and drug listing information.
 - What registration and listing information (including labeling) to submit.
 - Test the performance of FDA's electronic system for this type of submission.
 - **Mandatory** (1 June 09)



Drug Listing Data Elements- Standard Terminology for SPL

- Product
 - Proprietary and nonproprietary name and code (FDA DRLS)
 - Ingredients
 - Active and inactive ingredient and active moiety name and code (Unique Ingredient Identifier (UNII) from FDA SRS)
 - Active and inactive ingredient strength (NCI Thesaurus, UCUM)
 - Dosage form (NCI Thesaurus)
 - Appearance (imprint, color, shape, size, score, coating, symbol) (NCI Thesaurus and HL7)
 - Route of administration (NCI Thesaurus)
 - DEA schedule (NCI Thesaurus)
- Packaging
 - package type (NCI Thesaurus), quantity and code (FDA DRLS)

Courtesy of Randy Levin, MD,
FDA



Unique Ingredient Identifier (UNII) Codes

- Joint FDA/USP Substance Registration System (SRS) to support health information technology initiatives by generating unique ingredient identifiers (UNIIs) for substances in drugs/biologics.
- Non-proprietary, free, unique, unambiguous, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.
- FDA assigns UNII code.

See:
www.fda.gov/oc/datacouncil/SRS.htm



Unique Ingredient Identifier (UNII) Codes

- CBER to notify industry through formal regulatory correspondence.
 - Confirmation of UNII Codes
 - Other DLDE requirements
 - Necessary to list electronically (June 2009)



SPL Terminology

- Only controlled terminology permitted in SPL.
- Terminology lists located on FDA Data Standards Council's SPL web page:
<http://www.fda.gov/oc/datacouncil/spl.html>

SPL Terminology

Only controlled terminology is permitted in SPL documents

- Terminology lists are on FDA Data Standards Council's SPL web page:
<http://www.fda.gov/oc/datacouncil/spl.html>

- [Route of administration](#)
- [Dosage form](#)
- [Package type](#)
- [Units of measure and units of presentation](#)
- [Color](#)
- [Shape](#)
- [Coating](#)
- [Size](#)
- [Scoring](#)
- [Imprint codes](#)
- [Symbols](#)
- [SPL DEA Schedule](#)
- [Section headings](#)
- [Code system object identifiers \(OIDs\)](#)
- [Document Type including Content of Labeling Type](#)
- [Time Units: Unified Code for Units of Measure \(UCUM\)](#)
- [Substances/Unique Ingredient Identifiers \(UNIs\)](#)
- [Business Operation](#)
- [Marketing Category](#)
- [Marketing Status](#)
- [Equivalence Codes](#)
- [Flavor](#)

Outreach

- Webinars-Biologic Drug Products Sessions
 - Held on 5/15/08, 8/14/08
 - SPL R4 Training – DIA Web Conference – September 9, 2008
- CBER SPL Public Meeting tentatively scheduled for November 17th, 2008.
 - In depth overview of:
 - Content of Labeling
 - Electronic Drug Registration and Drug Listing
 - Drug Listing Data Elements
 - Vendor Challenge
- Future SPL R4 Training/Meetings
 - SPL R4 Meeting – DIA F2F – October 29-30, 2008



FDA Data Standards Council-Supporting Documentation

- <http://www.fda.gov/oc/datacouncil/spl.html>
 - Directions for obtaining the SPL standard and schema from HL7
 - Links to the SPL FDA Implementation Guide, the companion document to the HL7 SPL standard providing additional details on creating SPL files
 - Link to the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Content of Labeling*
 - Link to the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format-Drug Establishment Registration and Drug Listing*
 - Style sheet files for viewing SPL content of labeling files
 - Sample SPL content of labeling files



Thank You

General Questions:

vada.perkins@fda.hhs.gov

Technical Questions:

spl@fda.hhs.gov

- More information about UNII codes and the FDA SRS is available at:
 - SRS@cder.fda.gov
 - <http://www.fda.gov/oc/datacouncil/SRS.htm>